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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,403	12/08/2003	Thomas E. Barta	3124/9A/US (6794-000017/D)	4538
28997	7590	02/28/2006	EXAMINER	
HARNESS, DICKEY, & PIERCE, P.L.C 7700 BONHOMME, STE 400 ST. LOUIS, MO 63105			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/730,403

Applicant(s)

BARTA ET AL.

Examiner

Celia Chang

Art Unit

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This application is a divisional of SN 09/989,943.

A preliminary amendment was filed on Dec. 8, 2003. Claims 9-13, 16-25, 27-28, 32-33, 36-40, 42-46, 48-49, 55-56, 63, 67-68, 70-71, 74-78, 89-90, 92-95, 100-104 have been canceled. Claims 1-8, 14-15, 26, 29-31, 34-35, 41, 47, 50-54, 57-62, 64-66, 69, 72-73, 79-88, 91, 96-99, 105-110 and newly added 111-113 are pending.

2. Claims 1-8, 14-15, 26, 29-31, 34-35, 41, 47, 50-54, 57-62, 64-66, 69, 72-73, 79-88, 91, 96-99, 105-113 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 27-39 of U.S. Patent No. 6,890,937 or claims 1-19 or US 6,541,489. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a more limited scope (Z is O) which is fully embraced by the issued claims (Z is O, S, SO, N). One having ordinary skill in the art in possession of the issued claims would be in possession of the more limited scope of the instant claims because one would expect all the compounds of the generic scope to have similar activity.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 1-8, 14-15, 26, 29-31, 34-35, 41, 47, 50-54, 57-62, 64-66, 69, 72-73, 79-88, 91, 96-99, 105-110 are directed to the same invention as that disclosed in the commonly assigned US 6,890,937 or US 6,541,489. Please note that the generic claims of US 6,890,937 or US 6,541,489 fully embraced the instantly limited Z is O compounds. The issued claims guided by the explicitly disclosed anticipatory species (such as '937, col. 449-501 examples 62 and 63, not an exhausted listing of many anticipatory compounds) would guide one skilled in the art to the instant invention. It is noted that the instant inventive entity and the issued claims are *not the same*. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of the instant invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A *terminal disclaimer* has **no** effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

4. Claims 59-62, 64-66, 69, 72-73, 79-88, 91, 96-99 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for osteoarthritis or rheumatoid arthritis (CA 136, CA 131), does not reasonably provide enablement for the claimed scope encompassing all condition related to matrix metalloprotease activity in tissue destruction, fibrotic disease, matrix weakening, defective injury repair, cardiovascular disease, pulmonary disease, kidney disease and central nervous system disease (scope of enablement rejection). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with these claims .

The specification provided limited description and inhibiting activity on the claimed compound to be active on cartilage aggrecanase. Such limited activity failed to support the instantly claimed scope encompassing an enormous disorder for which cartilage has not been known to have any relationship to the etiology or symptom of the disorder. While inhibition of

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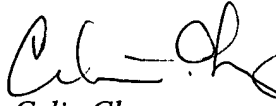
aggrecanase activity in cartilage has been correlated to treating rheumatoid arthritis or osteoarthritis no nexus of such activity in the cartilage tissue can be extrapolated to the claimed scope of diseases. No documentation in the record that compounds having similar structure as the claims were demonstrated to have such enormous diversity of therapeutic efficacy.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Feb. 23, 2006


Celia Chang
Primary Examiner
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Continuation of Disposition of Claims: Claims pending in the application are 1-8,14,15,26,29-31,34,35,41,47,50-54,57-62,64-66,69,72,73,79-88,91,96-99 and 105-113.

Continuation of Disposition of Claims: Claims rejected are 1-8,14,15,26,29-31,34,35,41,47,50-54,57-62,64-66,69,72,73,79-88,91,96-99 and 105-113.